

## **Board of Pharmacy**

### **Initial Statement of Reasons**

Subject Matter of Proposed Regulation: Pharmacist Identification, Pharmacy Self Assessment, Pharmacist Candidates, Continuing Education, Fees, Partial Filling of Schedule II prescriptions

Title 16 Sections Affected: 1706.2, 1712, 1715, 1715.5, 1717, 1719, 1720, 1720.1, 1725, 1726, 1727, 1728, 1732, 1732.05, 1732.1, 1732.2, 1732.3, 1732.4, 1732.5, 1732.6, 1732.7, 1745, 1749, 1750

#### Specific Purpose of the Proposed Changes:

Proposed amendments to section 1706.2 relocates provisions from section 1720 related to the abandonment of applications.

Proposed amendments to section 1712 specifies the requirements of electronic systems used in pharmacies to record the identity of the reviewing pharmacist.

Proposed amendments to section 1715 replace the existing self-assessment forms for community and hospital pharmacies with new forms reflecting recent changes to pharmacy law.

Proposed amendment to section 1715.5 is repealed.

Proposed amendments to section 1717 is amended to make technical corrections and to relocate the provisions of subdivision (e) to section 1712.

Proposed amendments to section 1719 is amended to delete the existing provisions and to recognize schools of pharmacy that are granted candidate status or full accreditation by the Accreditation Council for Pharmacy Education (ACPE).

Proposed amendments to section 1720 is amended to conform to the examination structure specified in Senate Bill 361 (Chapter 539, Statutes of 2004) and to delete provisions related to application abandonment that are relocated to section 1706.2.

Proposed amendments to section 1720.1 deletes the existing provisions and deems graduates of foreign pharmacy schools who are certified by the Foreign Pharmacy Graduate Examination Committee (FPGEC) to have satisfied the degree and education requirements for licensure as a pharmacist.

Proposed amendments to section 1725 makes technical changes and conforms to the proposed language in section 1720 regarding recognized schools of pharmacy.

Proposed amendments to section 1726 deletes provisions relating to pharmacy preceptors.

Proposed repeal of section 1727 delete the existing provisions.

Proposed amendments to section 1728 deletes the existing provisions and establishes the requirements for pharmacist candidates to sit for the licensure examinations.

Proposed amendments to section 1732 revises and updates definitions related to continuing education.

Proposed amendments to section 1732.05 reorganizes and recasts existing provisions relating to continuing education accreditation agencies.

Proposed amendments to section 1732.1 reorganizes and recasts existing provisions relating to continuing education providers.

Proposed amendments to section 1732.2 reorganizes and recasts existing provisions relating to continuing education providers accredited by the Board of Pharmacy.

Proposed amendments to section 1732.3 reorganizes and recasts existing provisions relating to continuing education courses.

Proposed amendments to section 1732.4 makes minor technical changes.

Proposed amendments to section 1732.5 makes minor technical changes.

Proposed amendments to section 1732.6 makes minor technical changes.

Proposed amendments to section 1732.7 makes minor technical changes.

Proposed amendments to section 1745 revises existing provisions relating to the partial filling of Schedule II controlled substance prescriptions.

Proposed amendments to section 1749 makes minor technical changes and eliminates fees that are no longer necessary. The fees for a foreign pharmacy graduate application and providers of education are eliminated to conform with changes proposed in this rulemaking.

Proposed repeal of section 1750 because the board can no longer issue such a license.

#### Factual Basis/Rationale

##### Section 1706.2

This change consolidates provisions related to the abandonment of applications.

##### Section 1712

Senate Bill 1913 (Chapter 695, Statutes of 2004) amended Business and Professions Code section 4115 to allow the use of systems approved by board regulations and this regulation implements that provision.

##### Section 1715

Existing versions of the pharmacy self assessment forms require updating to reflect numerous recent changes to pharmacy law.

##### Section 1715.5

This section is repealed because Senate Bill 151 (Chapter 406, Statutes of 2003) amended section 11165 of the Health and Safety Code to specify how pharmacies must report the dispensing of controlled substances.

#### Section 1717

This section is amended to make technical corrections and to relocate the provisions of subdivision (e) to section 1712.

#### Section 1719

This change will allow the board to issue intern pharmacist licenses to students in pharmacy schools with candidate status and for the board to allow graduates of pharmacy schools with candidate status to sit for the licensing examinations. Schools with candidate status are at the penultimate step of accreditation, but final accreditation can occur after students have been enrolled and need to obtain internship hours or to be qualified to take the licensure examinations.

#### Section 1720

These changes are made to conform to the examination structure specified in Senate Bill 361 (Chapter 539, Statutes of 2004) and to delete provisions related to application abandonment that are relocated to section 1706.2.

#### Section 1720.1

Senate Bill 1913 (Chapter 695, Statutes of 2004) requires graduates of foreign pharmacy schools to become certified by the FPGEC. FPGEC has the same degree and education requirements specified in section 4200 which makes board evaluation of those standards redundant.

#### Section 1725

These are technical changes and conforms to the proposed language in section 1720 regarding recognized schools of pharmacy.

#### Section 1726

Interns are no longer required to be supervised by preceptors. Accordingly, references to preceptors are eliminated.

#### Section 1727

Senate Bill 1913 (Chapter 695, Statutes of 2004) establishes the standards for issuing intern pharmacist licenses in section 4208 of the Business and Professions Code and are inconsistent with existing provisions of this section.

#### Section 1728

The proposed regulation will streamline the board's application process by requiring pharmacist candidates to have completed all other requirements for licensure prior to applying to take the licensure examinations. The intern hour requirements have been amended to eliminate the first year

maximum and preceptor supervision requirements to reflect changes to the pharmacy curriculum in ACPE accredited pharmacy schools.

#### Section 1732

The proposed regulation would eliminate unnecessary definitions.

#### Section 1732.05

The changes update and clarify existing requirements for continuing education accreditation agencies.

#### Section 1732.1

The changes update and clarify existing requirements for continuing education providers.

#### Section 1732.2

The changes update and clarify existing requirements for Board of Pharmacy accredited continuing education providers.

#### Section 1732.3

The changes update and clarify existing requirements for continuing education courses.

#### Section 1732.4

The proposed changes make minor technical changes.

#### Section 1732.5

The proposed changes make minor technical changes.

#### Section 1732.6

The proposed changes make minor technical changes.

#### Section 1732.7

The proposed changes make minor technical changes.

#### Section 1745

Changes made by Senate Bill 151 (Chapter 406, Statutes of 2003) allow the period for partial filling to be extended to 60 days and expands the authority to perform partial fills when a pharmacy does not have an adequate supply to fill the entire prescription in conformance with 21CFR section 1306.13. These changes will provide patients and pharmacists with greater flexibility when handling Schedule II prescriptions.

## Section 1749

The proposed regulation includes minor technical changes and the following substantive changes:

1. Subdivision (l) eliminates language relating to the extension of an intern pharmacist license in conformance with Business and Professions Code section 4208 which prohibits the extension or renewal of an intern pharmacist license.
2. Subdivision (m) is eliminated because this fee is specified in statute (Business and Professions Code section 4400) and existing language duplicates that provision.
3. Subdivision (n) is eliminated to conform with changes to continuing education regulations proposed in this rulemaking.
4. Subdivision (p) is eliminated to conform with changes regarding foreign graduates proposed in this rulemaking.
5. Subdivision (r) is eliminated because the board no longer regulates medical device retailers.

## Section 1750

This section is repealed to conform with the repeal of its authorizing statute (section 11127 of the Health and Safety Code).

### Underlying Data

None.

### Business Impact

This regulation will not have a significant adverse economic impact on businesses. This initial determination is based on the absence of testimony indicating adverse economic impact regarding these rulemaking proposals at the informational hearings held by the board.

### Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

### Consideration of Alternatives

No reasonable alternative to the regulation would be either more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed regulation.